

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC.,

Plaintiff,

v.

IVANTIS, INC., ALCON RESEARCH LLC,
ALCON VISION, LLC AND ALCON INC.,

Defendants.

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C. A. No.: 21-1317-GBW-SRF

JURY TRIAL DEMANDED


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**CONCISE STATEMENT OF ADDITIONAL FACTS IN SUPPORT OF SIGHT
SCIENCES, INC.'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY
JUDGMENT NO. 2 OF INVALIDITY FOR LACK OF WRITTEN DESCRIPTION**

YOUNG CONAWAY STARGATT &
TAYLOR, LLP

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

COOLEY LLP
Michelle S. Rhyu
Jeffrey Karr
Lauren Strosnick
Alissa Wood
Juan Pablo González
Angela R. Madrigal
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Orion Armon
1144 15th Street, Suite 2300
Denver, CO 80202-2686
(720) 566-4000

Dustin M. Knight
Joseph Van Tassel
Reston Town Center
11951 Freedom Drive, 14th Floor
Reston, VA 20190-5656
(703) 456-8000

Bonnie Fletcher Price
1299 Pennsylvania Avenue, NW, Suite 700
Washington, DC 20004-2400
(202) 842-7800

Attorneys for Sight Sciences, Inc.

Dated: November 2, 2023

1. A POSA would understand from the specification that the inventors possessed the inventions in the Asserted Claims that contain one of the limitations that Defendants collectively refer to as the “Block Limitation” (*see* D.I. 302, ¶2). (Ex. 90 (Downs Reb.) ¶¶1104-1117.)

2. A POSA would not have understood the Asserted Claims that contain a Block Limitation to be functionally-defined “genus claims,” as each claim includes additional limitations related to providing a support that “does not significantly block” fluid flow, that narrow the scope of these claims. (Ex. 90 (Downs Reb.) ¶¶1106-1108; Ex. 93 (Downs 9/28 Tr.) 35:7-25.)

3. A POSA would understand that the specification of the Asserted Patents provides numerous examples of supports that would satisfy the Block Limitation, including, *e.g.*, those discussed in connection to Figures 5B-12H. (*See, e.g.*, ’443, Figs. 5B-12H; Ex. 90 (Downs Reb.) ¶¶1109-1115; Ex. 93 (Downs 9/28 Tr.) 130:14-132:4.)

4. Dr. Downs did not admit that the specification of the Asserted Patents provides no examples of supports that achieve the Block Limitation function. Rather, Dr. Downs identified examples of supports in the specification that would satisfy the Block Limitation. (Ex. 90 (Downs Reb.) ¶¶1109-1115.) Dr. Downs testified that the device in Figure 9A/B, for example, would satisfy the Block Limitation. (Ex. 93 (Downs 9/28 Tr.) 130:14-132:4 (“Q: And what would your educated guesses about that be? A. That it would not substantially interfere with flow.”).)

5. The Asserted Patents provide instructive examples of supports that would not satisfy the Block Limitation, including, *e.g.*, solid-walled tubular stents inserted into Schlemm’s canal. (Ex. 90 (Downs Reb.) ¶1109; Ex. 93 (Downs 9/28 Tr.) 37:11-21, 85:16-87:8, 87:13-19, 95:6-16.)

6. The Asserted Patents also provide common structural features of supports that a POSA would relate to the Block Limitation function, including scaffolding and minimal contact with Schlemm’s canal (including, in particular, the interfaces with the trabecular meshwork and

the collector channels). (*See* '443, 10:61-65 (“A common characteristic of the support configurations described here is that they need not have continuous or extensive contact with a wall of Schlemm’s canal. Indeed, many of the described devices . . . have minimal tangential, periodic, or sporadic contact with the wall.”), 11:30-38; Ex. 90 (Downs Reb.) ¶¶1109-1110, 1114.)

7. Based on the specification, a POSA would have been able to visualize or recognize supports that would or would not satisfy the Block Limitation. (*See* Ex. 90 (Downs Reb.) ¶¶1109-1110, 1114; Ex. 93 (Downs 9/28 Tr.) 85:16-87:19, 95:6-96:11, 130:14-132:4.) This Court has already acknowledged this: “[a POSA] reading this disclosure would understand the relationship between the support’s contact with the canal walls and the amount of fluid outflow and would appreciate that the support can be designed in a manner to minimize the impact. A person of ordinary skill would be able to distinguish between supports that substantially interfere and those that do not based on a review of the Asserted Patents’ written description.” (D.I. 134 at 22-23 (internal citations omitted).)

8. Sight disputes Defendants’ mischaracterization and misapplication of Dr. Downs’s deposition testimony. The portion of Dr. Downs’s testimony that Defendants identify where he references a hypothetical support that had 20 percent surface area contact with Schlemm’s canal but that fully blocked the trabecular meshwork (*see* Ex. 93 (Downs 9/28 Tr.) 129:7-24) reflects the POSA’s understanding—as expressly disclosed in the Asserted Patents—that it is especially important to minimize contact with the portions of Schlemm’s canal that interface with the trabecular meshwork and the collector channels. (*See* '443, 11:30-38.)

9. Each of the Asserted Claims containing a Block Limitation includes one or more additional structural limitations, including, e.g., fenestrations, radius of curvature, and/or surface area contact, that are associated with the “common characteristic”—*i.e.*, scaffolding and minimal

contact with Schlemm’s canal (including, in particular, the interfaces with the trabecular meshwork and the collector channels)—that the Asserted Patents teach are shared by supports that would not substantially interfere with flow. (Ex. 90 (Downs Reb.) ¶¶1106-1108; Ex. 93 (Downs 9/28 Tr.) 35:7-25, 89:7-15.)

10. A POSA would not have considered there to be a “vast universe of possible candidates” nor an “immeasurable swath of ‘supports’ ... that achieve the Block Limitation.” A POSA—considering the claims as a whole—would have considered their scope to be meaningfully limited. (*See* Ex. 90 (Downs Reb.) ¶¶1106-1108; Ex. 93 (Downs 9/28 Tr.) 35:7-25, 96:19-97:2.)

11. The field of the invention is the mechanical arts, involving structures for facilitating fluid flow in the eye. A POSA, having knowledge and experience with fluid mechanics and the design of intraocular implants, would have appreciated that the structural features taught by the Asserted Patents would lead to predictable effects on flow, based on understood scientific principles. (*See* Ex. 90 (Downs Reb.) ¶¶168-171, 1074-1081; *see also, e.g.*, Ex. 93 (Downs 9/28 Tr.) 69:3-20, 86:2-87:8; Ex. 99 (Downs 9/22 Tr.) 225:8-227:23, 228:12-14, 286:3-12.)

12. Defendants understood and used terms like those in the Block Limitation to describe how the Hydrus facilitates (and does not block) flow from the trabecular meshwork and into Schlemm’s canal. For example, Defendants documents show: “Windows along the length of the implant allow natural trabecular flow through the body of [the] device.” (*See* Ex. 21 (IVANTIS_SS_00415663) at 415712; *see also id.* at IVANTIS_SS_00415721 (“Microstent geometry allows for outflow through TM [trabecular meshwork] through open windows”); Ex. 9 (Kimball Tr.) 94:21-23 (testifying that the windows of the Hydrus Microstent have “multiple functions,” one of which is to “allow aqueous flow through the trabecular meshwork through that window”); Ex. 22 (IVANTIS_SS_00006997) at 7001 (“Hydrus Microstent also has 3 large

windows that face the trabecular meshwork to allow aqueous to easily pass through the trabecular meshwork into Schlemm’s canal.”); Ex. 23 (IVANTIS_SS_00276222) at 276226; *see also* Ex. 97 (Downs Op.) ¶¶87-89, 91, 95-96; Ex. 100 (Downs Reply) ¶¶45-49, 51-52, 62.)

13. Ivantis represented to the FDA that windows of the Hydrus were designed to and did enable flow from the trabecular meshwork into Schlemm’s canal. (Ex. 24 (IVANTIS_SS_00074707) at 74723 (“[REDACTED]”); *see also* Ex. 25 (IVANTIS_SS_00023750) at 23768; Ex. 97 (Downs Op.) ¶¶87-88, 91; Ex. 100 (Downs Reply) ¶49.)

14. Determining whether a support would or would not satisfy the Block Limitation does not always require modeling or testing of the support. A POSA would understand from the Asserted Patents that some supports would or would not block flow without any testing. (*See, e.g.*, Ex. 93 (Downs 9/28 Tr.) 37:11-21, 85:16-87:19, 95:6-96:11, 130:14-132:4; (Ex. 90 (Downs Reb.) ¶¶1109-1111, 1114.)

15. A POSA would understand that the amount of experimentation or modeling, if any, necessary for any particular device was routine and depends on the design. (Ex. 93 (Downs 9/28 Tr.) 67:9-15, 71:8-72:9, 116:15-117:5, 117:17-24; Ex. 90 (Downs Reb.) ¶1098.)

16. Defendants contend that a POSA would recognize that structures designed to minimize a support’s contact with the walls of Schlemm’s canal act to facilitate, not significantly block, flow. (*E.g.*, Ex. 87 (’443 IPR Pet.) 30, 39-41, 50; Ex. 88 (’443 IPR Reynard Decl.) ¶¶69-71, 92-93; Ex. 89 (Tanna Op.) ¶¶141, 150, 153-154, 157, 239, 443.) Defendants contend that no experimentation was required to determine that such devices do not block flow. (*Id.*)

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Melanie K. Sharp

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
Taylor E. Hallowell (No. 6815)
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
msharp@ycst.com
jhiggins@ycst.com
thallowell@ycst.com

COOLEY LLP
Michelle S. Rhyu
Jeffrey Karr
Lauren Strosnick
Alissa Wood
Juan Pablo González
Angela R. Madrigal
3175 Hanover Street
Palo Alto, CA 94304-1130
(650) 843-5000

Orion Armon
1144 15th Street, Suite 2300
Denver, CO 80202-2686
(720) 566-4000

Dustin M. Knight
Joseph Van Tassel
Reston Town Center
11951 Freedom Drive, 14th Floor
Reston, VA 20190-5656
(703) 456-8000

Bonnie Fletcher Price
1299 Pennsylvania Avenue, NW
Suite 700
Washington, DC 20004-2400
(202) 842-7800

Dated: November 2, 2023

Attorneys for Sight Sciences, Inc.

CERTIFICATE OF SERVICE

I, Melanie K. Sharp, Esquire, hereby certify that on November 2, 2023, I caused to be electronically filed a true and correct copy of Concise Statement of Additional Facts in Support of Sight Sciences, Inc.'s Opposition to Defendants' Motion for Summary Judgment No. 2 of Invalidity for Lack of Written Description with the Clerk of the Court using CM/ECF, which will send notification to the following counsel of record:

John W. Shaw
Karen E. Keller
Andrew E. Russell
Nathan R. Hoeschen
Shaw Keller LLP
I.M. Pei Building
1105 North Market Street, 12th Floor
Wilmington, DE 19801
jshaw@shawkeller.com
kkeller@shawkeller.com
arussell@shawkeller.com
nhoeschen@shawkeller.com

I further certify that on November 2, 2023, I caused a copy of the foregoing document to be served on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

BY E-MAIL:

Gregg LoCascio
Sean M. McEldowney
W. Todd Baker
Justin Bova
Steven Dirks
Socrates L. Boutsikaris
Kirkland & Ellis LLP
1301 Pennsylvania Avenue, N.W.
Washington, DC 20004
gregg.locascio@kirkland.com
sean.mceldowney@kirkland.com
justin.bova@kirkland.com
steven.dirks@kirkland.com
socrates.boutsikaris@kirkland.com

Jeanne M. Heffernan
Kat Li
Austin C. Teng
Ryan J. Melde
Lydia B. Cash
Kirkland & Ellis LLP
401 Congress Avenue
Austin, TX 78701
jheffernan@kirkland.com
kat.li@kirkland.com
austin.teng@kirkland.com
ryan.melde@kirkland.com
lydia.cash@kirkland.com

Ryan Kane
Nathaniel DeLucia
Laura Zhu
Emily C. Sheffield
Kirkland & Ellis LLP
601 Lexington Avenue
New York, NY 10022
ryan.kane@kirkland.com
nathaniel.delucia@kirkland.com
laura.zhu@kirkland.com
emily.sheffield@kirkland.com

Brian A. Verbus
Jacob Rambeau
300 N. LaSalle
Chicago, IL 60654
brian.verbus@kirkland.com
jake.rambeau@kirkland.com

Noah S. Frank
200 Clarendon Street
Boston, MA 02116
noah.frank@kirkland.com

/s/ Melanie K. Sharp
Melanie K. Sharp (No. 2501)